510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k122961

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine, Methamphetamine

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Amphetamine Urine Test (AMP 300)

Wondfo Methamphetamine Urine Test (MET 500)

G. Regulatory Information:

Product code	Classification	Regulation section	Panel
DKZ	Class II	21 CFR §862.3100: Test System, Amphetamine	Toxicology (91)
LAF	Class II	21 CFR §862.3610: Test System, Methamphetamine	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for Use

2. Indication(s) for use:

   Wondfo Amphetamine Urine Test (AMP 300):

   Wondfo Amphetamine Urine Test (AMP 300) is an immunochromatographic assay for the qualitative determination of d-Amphetamine in human urine at a cutoff concentration 300 ng/mL. The test is available in a Dip Card format and a

Cup format. It is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Wondfo Methamphetamine Urine Test (MET 500):

Wondfo Methamphetamine Urine Test (MET 500) is an immunochromatographic assay for the qualitative determination of D(+)-Methamphetamine in human urine at a cutoff concentration 500 ng/mL. The test is available in a Dip Card format and a Cup format. It is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

3. Special conditions for use statement(s):

   For prescription use

   For *in vitro* diagnostic use

4. Special instrument requirements:

   Not applicable, since the devices are visually read single use devices.

I. Device Description:

The AMP 300 and MET 500 Urine tests have two formats: Dip Card format and Cup format. The Dip Card format kit contains a test card and a separate Cup for urine collection. The Cup format kit contains a cup with a built-in test card. Both formats are available as a single test in a pouch with a desiccant. The desiccant is for storage purpose only. The sealed pouch is stable until the expiration date when stored at 4 to 30 ºC.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON® AMP 300 One Step Amphetamine Test Strip, ACON® AMP 300 One Step Amphetamine Test Device

   ACON® mAMP-500 One Step Methamphetamine Test Strip, ACON® mAMP-500 One Step Methamphetamine Test Device

2. Predicate 510(k) number(s):

   k041822, k033299

3. Comparison with predicate:

   Wondfo AMP 300 Urine Test comparison to the predicate device

Item	Candidate Devices: Wondfo Amphetamine Urine Test (AMP 300)	Predicate Devices: ACON AMP 300 One Step Amphetamine Test Strip; ACON AMP 300 One Step Amphetamine Test Device (k041822)
Indication(s) for Use	For the qualitative determination of Amphetamine in human urine.	Same
Calibrator	d-Amphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut Off Values	300 ng/mL	Same
Configurations	Cup, Dip Card	Test Strip, Test Device
Intended Use	Prescription Use; Not for Point-of-Care Use	Prescription Use; for Point-of-Care Use

Wondfo MET 500 Urine Test comparison to the predicate device

Item	Candidate Devices: Wondfo Methamphetamine Urine Test (MET 500)	Predicate Devices: ACON mAMP 500 One Step Methamphetamine Test Strip; ACON mAMP 500 One Step Methamphetamine Test Device (k033299)
Indication(s) for Use	For the qualitative determination of D(+)-Methamphetamine in human urine.	Same
Calibrator	D(+)-Methamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut Off Values	500 ng/mL	Same

Configurations	Cup, Dip Card	Test Strip, Test Device
Intended Use	Prescription Use; Not for Point-of-Care Use	Prescription Use; for Point-of-Care Use

K. Standard/Guidance Document Referenced (if applicable):

The sponsor has followed two FDA issued guidance: *In Vitro* Diagnostic Devices: Guidance fore the Preparation of 510(k) Submission, HHS Publication FDA 97-4224; Premarket Submission and labeling Recommendations for Drugs of Abuse Screening Tests, Draft Guidance, December 2, 2003.

L. Test Principle:

The AMP 300 and MET 500 Urine Tests employ lateral flow immunochromatographic technology, and are based on competitive binding for the qualitative detection of d-Amphetamine and D(+)-Methamphetamine respectively in human urine. Each assay uses a monoclonal antibody-dye conjugate against drug with gold chloride, fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody coated in a nitrocellulose membrane. When the absorbent end is immersed into the urine specimen, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When the sample drug level is zero or below the target cut off, the antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that indicates a negative result. When the sample drug level is at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result. To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region(C) of the device.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   The precision study was conducted by three operators each testing one of the three lots of the devices used in the study. Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cutoff, +25% cut off, +50% cut off , +75% cut off and +100% cut off. Samples were prepared, concentrations of each sample confirmed by GC/MS, and then each sample was divided in to 300 aliquots. The 300 sample aliquots were divided in to 12 sets of 25 (one set per lot per run for each format). For each concentration, tests were performed two runs per day per lot for 25 days. The results obtained are summarized in the following

tables.

AMP 300 Urine Tests

Cup format

Samples / Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W0770901CU2	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
W0770902CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
W0770903CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Samples / Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W0770901P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
W0770902P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
W0770903P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

MET 500 Urine Tests

Cup Format

Samples / Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W1170901CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
W1170902CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
W1170903CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Samples / Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W1170901P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
W1170902P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
W1170903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

These devices have internal process control. A colored line appearing in the control region confirms sufficient sample volume flowed through the membrane by capillary action. Users are informed that the test is invalid if a line fails to appear in the control regions.

Quality control materials are not supplied with these devices. However, as a

good laboratory testing practice to confirm the test procedure and to verify proper test performance, the sponsor recommends that the user test these devices using external controls following the appropriate federal, state and local guidelines.

Accelerated stability and real time stability tests were performed on three lots of dip cards and cups for AMP 300 and MET 500 urine test devices using samples at -50% cutoff and +50% cutoff, and negative urine. The stability study results support the claimed shelf life of 18 months at 4 to 30 ºC. The transport simulation studies supports that the devices are stable for 3 weeks when exposed to extreme temperatures of -20 ºC and 40 ºC.

d. Detection limit:

Analytical performance of the device around the cutoff is described in item M1f (Assay cut-off) below.

e. Analytical specificity:

Cross Reactivity Studies:

To evaluate cross reactivity of the AMP 300 and MET 500 Urine Test devices, the target drug, drug metabolites and the structurally related compounds that may cross-react with the target drugs are tested with three lots of the devices using both the Cup and the Dip Card formats. All compounds are added to drug-free urine to a high target concentration of 100,000 ng/mL. Compounds that tested positive at 100,000 ng/mL concentration were serially diluted and retested until the concentration at which the initial negative result is obtained. Two different groups of operators were assigned to test blinded samples (three operators tested the Cup format and three tested the Dip Card format). Each sample testing and reading is performed by a laboratory assistant using a device from one lot. Each result is confirmed by two other laboratory assistants with relevant experience. Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result and then multiplying by 100. Identical results were obtained with the cup and dip card formats for the AMP 300 and MET 500 Urine tests. Summary of the study results is as follows:

Amphetamine 300 Urine Tests (Cup and Dip Card formats)

AMP(Amphetamine) (d-Amphetamine, Cutoff=300 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
d-Amphetamine	300	100%
l-Amphetamine	17500	1.7%
dl-Amphetamine	850	35.3%
(+/-) 3,4-methylenedioxyamphetamine	1000	30.0%

(MDA)		
Phentermine	1000	30.0%
β-Phenylethylamine	100000	0.3%
Tyramine	100000	0.3%
p-Hydroxynorephedrine	100000	0.3%
Phenylpropanolamine	>100,000	Not detected
(±)Phenylpropanolamine	>100,000	Not detected
p-Hydroxyamphetamine	100,000	0.3%
d/l-Norephedrine	100,000	0.3%
d-Methamphetamine	>100,000	Not detected
l-Methamphetamine	>100,000	Not detected
(+/-)3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	Not detected
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	Not detected
Benzphetamine	>100,000	Not detected
Ephedrine	>100,000	Not detected
l-Ephedrine	>100,000	Not detected
l-Epinephrine	>100,000	Not detected
d/l-Epinephrine	>100,000	Not detected

Methamphetamine 500 Urine Tests (Cup and Dip Card formats)

MET(Methamphetamine) (D(+)-Methamphetamine, Cutoff=500 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
D(+)-Methamphetamine	500	100%
D-Amphetamine	50000	1.0%
Chloroquine	10000	5.0%
(+/-)-Ephedrine	25000	2.0%
(-)-Methamphetamine	10000	5.0%
(+/-)3,4-methylenedioxumethamphetamine (MDMA)	1000	50.0%
β-Phenylethylamine	25000	2.0%
Trimethobenzamide	5000	10.0%
d/l-Amphetamine	75,000	0.7%
p-Hydroxymethamphetamine	15,000	3.3%
Mephentermine	25,000	2.0%
(1R,2S)-(-)-Ephedrine	50,000	1.0%
l-Phenylephrine	100,000	0.5%

Interference Studies:

Potential interferences of the test devices with 100 µg/mL of structurally

unrelated compounds (endogenous compounds, drugs, drug metabolites) that are commonly found in the urine was evaluated using three lots of the cup and the dip card using urine controls at -100% and ±25% cutoff concentration of each analyte. Two different groups of operators were assigned to test blinded samples (three operators tested the Cup format and three tested the Dip Card format). Each sample testing and reading is performed by a laboratory assistant using a device from one lot. Each result is confirmed by two other laboratory assistants with relevant experience. Identical results were obtained with the cup and dip card formats for the AMP 300 and MET 500 Urine tests. The following compounds were found not to cross react when tested at 100 µg/mL concentration.

Amphetamine 300 Urine Tests (Cup and Dip Card formats)

4-Acetamidophenol	Clonidine	Hydrocodone	Oxalic acid
Acetophenetidin	Cocaine hydrochloride	Hydrocortisone	Oxazepam
N-Acetylprocainamide	Codeine	O-Hydroxyhippuric acid	Oxolinic acid
Acetylsalicylic acid	Cortisone	3-Hydroxytyramine	Oxycodone
Aminopyrine	(-) Cotinine	Ibuprofen	Oxymetazoline
Amitryptyline	Creatinine	Imipramine	Papaverine
Amobarbital	Deoxycorticosterone	(-) Isoproterenol	Penicillin-G
Amoxicillin	Dextromethorphan	Isoxsuprine	Pentazocaine
Ampicillin	Diazepam	Ketamine	Pentobarbital
Ascorbic acid	Diclofenac	Ketoprofen	Perphenazine
Apomorphine	Diflunisal	Labetalol	Phencyclidine
Aspartame	Digoxin	Levorphanol	Phenelzine
Atropine	Diphenhydramine	Loperamide	Phendimetrazine
Benzilic acid	Doxylamine	Maprotiline	Phenobarbital
Benzoic acid	Ecgonine hydrochloride	Meperidine	Phetoin
Benzoylecgonine	Ecgonine methylester	Meprobamate	L-Phenylephrine
Bilirubin	(IR,2S)-(-)-Ephedrine	Methadone	β-Phenylethlamine
Brompheniramine	L-Ephedrine	Methylphenidate	Phenylpropanolamine
Caffeine	(-) Y Ephedrine	Morphine-3-Dglucuronide	Prednisolone
Cannabidiol	Erythromycin	Nalidixic acid	Prednisone
Cannabinol	β-Estradiol	Naloxone	Procaine
Chloralhydrate	Estrone-3-sulfate	Naltrexone	Promazine
Chloramphenicol	Ethyl-p-aminobenzoate	Naproxen	Promethazine
Chlordiazepoxide	Fenfluramine	Niacinamide	D,L-Propanolol
Chlorothiazide	Fenoprofen	Nifedipine	Propiomazine
(±)Chlorpheniramine	Furosemide	Norcodein	D-Propoxyphene
Chlorpromazine	Gentisic acid	Norethindrone	Quinidine
Chlorquine	Hemoglobin	D-Norpropoxyphene	Quinine
Cholesterol	Hydralazine	Noscapine	Ranitidine
Clomipramine	Hydrochlorothiazide	D,L-Octopamine	Salicylic acid
Secobarbital	Tetrahydrocortisone	D,L-Thyroxine	Tryptamine
Serotonin	Tetrahydrozoline	Tolbutamine	D, L-Tyrosine
Sulfamethazine	Δ9-THC-COOH	Triamterene	Uric acid

Sulindac	Thebaine	Trifluoperazine	Verapamil
Temazepam	Thiamine	Trimethoprim	Zomepirac
Tetracycline	Thioridazine	Trimipramine	Tryptamine

Methamphetamine 500 Urine Tests (Cup and Dip Card formats)

Acetamidophen	Diphenhydramine	Methylphenidal	D,L-Propanolol
Acetophenetidin	Doxylamine	Methyprylon	D-Propoxyphene
N-Acetylprocainamide	Ecgonine hydrochloride	Morphine-3-β-Dglucuronide	D-Pseudoephedrine
Acetylsalicylate	Ecgonine methyl ester	Nalidixic acid	Quinidine
Aminopyrine	Erythromycin	Nalorphine	Quinine
Amitryptyline	β-Estradiol	Naloxone	Ranitidine
Amobarbital	Estrone-3-sulfate	Naltrexone	Salicylic acid
Amoxicillin	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Ampicillin	Fenoprofen	Niacinamide	Serotonin (5-Hydroxytyramine)
Apomorphine	Furosemide	Nifedipine	Sulfamethazine
Aspartame	Gentisic acid	Norcodein	Sulindac
Atropine	Glucuronide	Norethindrone	Temazepam
Benzilic acid	Glutethimide	Noroxymorphone	Tetracycline
Benzoic acid	Guaifenesin	D-Norpropoxyphene	Tetrahydrocortisone, 3-Acetate
Benzoylecgonine	Hippuric acid	Noscapine	Tetrahydrocortisone 3 (β-D glucuronide)
Butabartital	Hydralazine	Nylidrin	Tetrahydrozoline
Cannabidiol	Hydrochlorothiazide	D,L-Octopamine	Thebaine
Chloralhydrate	Hydrocodone	Oxalic acid	Thiamine
Chloramphenicol	Hydrocortisone	Oxazepam	Thioridazine
Chlordiazepoxide	O-Hydroxyhippuric acid	Oxolinic acid	Tolbutamine
Chlorothiazide	3-Hydroxytyramine	Oxycodone	Triamterene
Chlorpromazine	Ibuprofen	Oxymetazoline	Trifluoperazine
Cholesterol	Imipramine	Papaverine	Trimethoprim
Clomipramine	(-) Isoproterenol	Penicillin-G	Trimipramine
Clonidine	Isoxsuprine	Pentazocine	D, L-Tryptophan
Cocaine hydrochloride	Ketamine	Pentobarbital	Tyramine
Codeine	Ketoprofen	Perphenazine	D, L-Tyrosine
Cortisone	Labetalol	Phencyclidine	Uric acid
(-) Cotinine	Levorphanol	Phenelzine	Verapamil
Creatinine	Loperamide	Phenobarbital	Zomepirac
Deoxycorticosterone	Loxapine succinate	Prednisolone	Digoxin
Dextromethorphan	Maprotiline	Phenylpropanolamine	Methaqualone
Diazepam	Meperidine	Prednisone	Promethazine
Diclofenac	Meprobamate	Procaine	
Diflunisal	Methadone	Promazine	

pH:

The pH of an aliquoted negative urine pool was adjusted to a pH range of 4.00 to 9.00 in increments of one pH, and was spiked with ±25% cutoff concentration of each analyte. Two different groups of operators were assigned to test blinded samples (three operators tested the Cup format and three tested the Dip Card format). Each sample testing and reading is performed by a laboratory assistant using a device from one lot. Each result is read by two other laboratory assistants with relevant experience. Identical results were obtained with the cup and dip card formats for the AMP 300 and MET 500 Urine tests. The pH range of 4.00 to 9.00 does not affect the accuracy of the cup and dip card formats for the AMP 300 and MET 500 Urine tests.

Specific gravity:

The specific gravity of an aliquoted negative urine pool was adjusted to 1.000, 1.003, 1.007, 1.008, 1.017, 1.019, 1.020, 1.025, 1.030, 1.031, 1.033 and 1.035, and was spiked with ±25% cutoff concentration of each analyte. Two different groups of operators were assigned to test blinded samples (three operators tested the Cup format and three tested the Dip Card format). Each sample testing and reading is performed by a laboratory assistant using a device from one lot. Each result is read by two other laboratory assistants with relevant experience. Identical results were obtained with the cup and dip card formats for the AMP 300 and MET 500 Urine tests. The specific gravity range of 1.000 to 1,035 does not affect the accuracy of the cup and dip card formats for the AMP 300 and MET 500 Urine tests.

f. Assay cut-off:

The assay cutoff is established using 25 clinical samples ranging in concentrations from ~ -50% to ~ +50% of amphetamine cutoff of 300 ng/mL for AMP 300 urine test, and 25 clinical samples ranging in concentrations from ~ -50% to ~ +50% of methamphetamine cutoff of 500 ng/mL for MET 500 urine test. Additionally, 125 drug-free urine samples were spiked with amphetamine and 125 drug-free urine samples were spiked with methamphetamine to prepare samples at concentrations of -50%, -25%, cutoff, +25% and +50% respectively of AMP cutoff of 300 ng/mL and MET cutoff of 500 ng/mL. The true drug concentrations in each sample were read by GC/MS. Each sample is tested with three lots of the cup format and the dip card format by two separate groups of operators (one for the cup format and one for the dip card format). Three operators in each group who are blind to the samples, performed the test. Each result was confirmed by two other laboratory assistants with relevant experience. The results of the assay cutoff study are as follows:

AMP 300 Urine Tests

Cup Format

Concentration ng/mL	Cutoff range	n	W0770901CU2		W0770902CU2		W0770903CU2		Total	
			-	+	-	+	-	+	-	+
150	–50% Cutoff	30	30	0	30	0	30	0	90	0
225	–25% Cutoff	30	30	0	30	0	30	0	90	0
300	Cutoff	30	1	29	2	28	3	27	6	84
375	+25% Cutoff	30	0	30	0	30	0	30	0	90
450	+50% Cutoff	30	0	30	0	30	0	30	0	90

Dip Card Format

Concentration ng/mL	Cutoff range	n	W0770901P		W0770902P		W0770903P		Total	
			-	+	-	+	-	+	-	+
150	–50% Cutoff	30	30	0	30	0	30	0	90	0
225	–25% Cutoff	30	30	0	30	0	30	0	90	0
300	Cutoff	30	3	27	2	28	2	28	7	83
375	+25% Cutoff	30	0	30	0	30	0	30	0	90
450	+50% Cutoff	30	0	30	0	30	0	30	0	90

MET 500 Urine Tests

Cup Format

Concentration ng/mL	Cutoff range	n	W1170901CU2		W1170902CU2		W1170903CU2		Total	
			-	+	-	+	-	+	-	+
250	–50% Cutoff	30	30	0	30	0	30	0	90	0
375	–25% Cutoff	30	30	0	30	0	30	0	90	0
500	Cutoff	30	3	27	3	27	2	28	8	82
625	+25% Cutoff	30	0	30	0	30	0	30	0	90
750	+50% Cutoff	30	0	30	0	30	0	30	0	90

Dip Card Format

Concentration ng/mL	Cutoff range	n	W1170901P		W1170902P		W1170903P		Total	
			-	+	-	+	-	+	-	+
250	–50% Cutoff	30	30	0	30	0	30	0	90	0
375	–25% Cutoff	30	30	0	30	0	30	0	90	0
500	Cutoff	30	2	28	2	28	3	27	7	83
625	+25% Cutoff	30	0	30	0	30	0	30	0	90
750	+50% Cutoff	30	0	30	0	30	0	30	0	90

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed by comparing the AMP 300 and

MET 500 Urine Tests (both the Dip Card and the Cup formats) with the GC/MS reference method. Eighty unaltered samples collected from a drug addiction recovery center were studied using one lot of each format for each analyte. These samples range from drug-free urine (10), < -50% cutoff, -50% cutoff ~ cutoff, Cutoff ~ +50% cutoff and > +50% cutoff of AMP. Each result was read by three experienced laboratory assistants. A summary of results of the method comparison studies is as follows:

AMP 300 Urine Tests

Cup Format

Results read by lab assistants (group 1)	Wondfo Cup Format Device Results	Negative by GC/MS (drug-free)	Low Negative by GC/Ms (less than -50% cutoff)	Near Cutoff Negative by GC/MS (between -50% cutoff and cutoff)	Near Cutoff Positive by GC/MS (between the cutoff and +50% cutoff)	High Positive by GC/MS (greater than +50% cutoff)
Viewer A	Positive	0	0	2	29	11
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	1	29	11
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	17	12	0	0

Dip Card Format

Results read by lab assistants (group 2)	Wondfo Dip Card Format Device Results	Negative by GC/MS (drug-free)	Low Negative by GC/Ms (less than -50% cutoff)	Near Cutoff Negative by GC/MS (between -50% cutoff and cutoff)	Near Cutoff Positive by GC/MS (between the cutoff and +50% cutoff)	High Positive by GC/MS (greater than +50% cutoff)
Viewer A	Positive	0	0	1	29	11
	Negative	10	17	12	0	0
Viewer B	Positive	0	0	1	29	11
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	17	12	0	0

Discordant Results of AMP 300 Urine Tests

Viewer	Sample Number	GC/MS Result	Viewer Result
Cup Format			
Viewer A	AMP3063	281	Positive
Viewer A	AMP3216	259	Positive
Viewer B	AMP3218	287	Positive
Viewer C	AMP3063	281	Positive
Dip Card Format			
Viewer A	AMP3218	287	Positive
Viewer B	AMP3216	259	Positive
Viewer C	AMP3063	281	Positive

MET 500 Urine Tests

Cup Format

Results read by lab assistants (group 1)	Wondfo Cup Format Device Results	Negative by GC/MS (drug-free)	Low Negative by GC/Ms (less than -50% cutoff)	Near Cutoff Negative by GC/MS (between -50% cutoff and cutoff)	Near Cutoff Positive by GC/MS (between the cutoff and +50% cutoff)	High Positive by GC/MS (greater than +50% cutoff)
Viewer A	Positive	0	0	2	20	20
	Negative	10	15	13	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	15	13	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	15	13	0	0

Dip Card Format

Results read by lab assistants (group 2)	Wondfo Dip Card Format Device Results	Negative by GC/MS (drug-free)	Low Negative by GC/Ms (less than -50% cutoff)	Near Cutoff Negative by GC/MS (between -50% cutoff and cutoff)	Near Cutoff Positive by GC/MS (between the cutoff and +50% cutoff)	High Positive by GC/MS (greater than +50% cutoff)
Viewer A	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

Viewer C	Positive	0	0	2	20	20
	Negative	10	15	13	0	0

Discordant Results of MET 500 Urine Tests

Viewer	Sample Number	GC/MS Result	Viewer Result
Cup Format			
Viewer A	MET5061	478	Positive
Viewer A	MET5216	474	Positive
Viewer B	MET5063	499	Positive
Viewer B	MET5215	421	Positive
Viewer C	MET5061	478	Positive
Viewer C	MET5063	499	Positive
Dip Card Format			
Viewer A	MET5063	499	Positive
Viewer B	MET5061	478	Positive
Viewer C	MET5061	478	Positive
Viewer C	MET5063	499	Positive

The results indicate a similar positive, negative, and overall agreement rates for both AMP 300 and MET 500 urine tests using the cup and the dip card formats. The overall average agreement between the Wondfo devices and GC/MS is represented in the following table:

Percent Agreement	AMP 300 Cup format	AMP 300 Dip Card format	MET 500 Cup format	MET 500 Dip Card format
Positive	100%	100%	100%	100%
Negative	96.7%	97.5%	95%	96.7%
Total	98.4%	98.8%	97.5%	98.4%

b. Matrix comparison:

Not applicable; these devices are for use with urine only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.